DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 2, 2016

Aston Medical
% Ms. Catherine Gloster
Gloster Biomedical International
577 North Hope Avenue
Santa Barbra, California 93110

Re: K103251
Trade/Device Name: Duocentric® Reversed Shoulder Prosthesis
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX
Dated: September 30, 2011
Received: October 3, 2011

Dear Ms. Gloster:

This letter corrects our substantially equivalent letter of October 28, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k): K103251

Duocentric® Reversed shoulder prosthesis: Aston® Medical

Indications for Use:

Implantation of a joint prosthesis is to be considered only when all other surgical options have been carefully examined and found less appropriate.

The Duocentric® Reversed shoulder prosthesis is indicated for use in case of gross rotator cuff deficiency including when it is associated with osteoarthritis, revision of previous arthroplasty or complex fracture of the humerus (3 fragments or more) in an older population (e.g. 65 years of age or older).

The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device.

The humeral stem is intended for use with cement when polished or without cement when coated with Hydroxyapatite. All other components are intended for cementless use only. The glenoid baseplate is intended for cementless application with the addition of three screws for fixation. It is coated with a double layer of pure Titanium and Hydroxyapatite on its posterior side.

Prescription Use _X_____	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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OCT 28 2011

SECTION 5: 510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of SMDA and 21CFR § 807.92

Submitted by:	Aston® Medical 19, rue Victor Grignard Zone Industrielle de Montreynaud 42000 Saint-Etienne France
Prepared By/Contact Person:	Catherine Gloster, M.Sc. RAC Regulatory Consultant Gloster Biomedical International 577 North Hope Ave Santa Barbara, CA 93110 - USA Phone: 805-679-1258 Email: c.gloster@GlosterBiomedical.com
Date Prepared:	October 28, 2011
Proprietary Name:	DUOCENTRIC® Reversed
Common Name:	Reverse shoulder prosthesis
Classification:	Class II, 21 CFR 888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis KWS
Predicate Devices:	**K091751** – Depuy Orthopaedic, Inc. USA – Depuy Delta Xtend Reverse Shoulder - cleared 7/14/2009 **K021478** – Depuy Orthopaedic, Inc. USA – Delta Shoulder – cleared 11/18/2003 **K100142** – Tornier, France – Aequalis Reversed Shoulder Prosthesis – cleared 5/6/2010 **K053274** – Zimmer, Inc. USA – Anatomical Shoulder™ Inverse/Reverse – cleared 1/25/2006
Device Description:	The Duocentric® Reversed shoulder prosthesis is a prosthesis that uses the biomechanical concepts of reverse shoulder arthroplasty as originally described by Paul Grammont.

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The Duocentric® Reversed shoulder prosthesis is composed of a humeral stem, a humeral baseplate, a humeral insert, a gleonosphere (Duoglene), and a glenoid baseplate. The humeral insert is made of ultra-high-molecular-weight polyethylene (UHMWPE), while all other components are made of wrought high nitrogen stainless steel M30NW. The humeral stem is intended for cemented use unless coated with hydroxyapatite (HA). The glenoid baseplate is coated with a double coating of pure titanium and hydroxyapatite (Ti/HA), is intended for cementless use, and is fixated with wrought high nitrogen stainless steel screws. The device is provided sterile.

The HA and Ti/HA coatings conform to ASTM standards ASTM F1185, ASTM F1609, and ASTM F1580 and are performed by Medical Coating (Vault-en-Velin, FR) according to their Master File MAF-1633.

Indication for Use:

Implantation of a joint prosthesis is to be considered only when all other surgical options have been carefully examined and found less appropriate.

The Duocentric® Reversed shoulder prosthesis is indicated for use in case of gross rotator cuff deficiency including when it is associated with osteoarthritis, revision of previous arthroplasty or complex fracture of the humerus (3 fragments or more) in an older population (e.g. 65 years of age or older).

The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device.

The humeral stem is intended for use with cement when polished or without cement when coated with Hydroxyapatite. All other components are intended for cementless use only. The glenoid baseplate is intended for cementless application with the addition of three screws for fixation. It is coated with a double layer of pure Titanium and Hydroxyapatite on its posterior side.

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Basis for substantial equivalence:	The Duocentric® Reversed shoulder prosthesis is substantially equivalent to the previously cleared devices: Depuy Delta Xtend Reversed Shoulder (K091751), Depuy Delta Shoulder (K021478), Tornier Aequalis Reverse Shoulder (K100142), and Zimmer Anatomical Reverse/Inverse Shoulder (K053274). This assessment is based on similarities in indications for use, materials, dimensions, design, packaging and sterilization processes and results of pre-clinical testing. The subject device does not raise any new issues of safety and effectiveness.
Performance Data:	Pre-clinical performance testing concluded that the Duocentric® Reversed shoulder finished product and its components met all pre-determined specifications and are adequate for their intended use. Clinical data were not required for this device. This product has been commercialized since 2003 in Europe and has shown to be safe and effective as shown by post-market data.